



IDAHO DEPARTMENT OF  
**HEALTH & WELFARE**

C.L. "BUTCH" OTTER – Governor  
RICHARD M. ARMSTRONG – Director

TAMARA PRISOCK—ADMINISTRATOR  
DIVISION OF LICENSING & CERTIFICATION  
DEBBY RANSOM, R.N., R.H.I.T. – Chief  
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**CERTIFIED MAIL: 7012 3050 0001 2128 4785**

September 4, 2015

Charlene Conilogue, Administrator  
Idaho Surgicenter North  
3369 A Merlin Drive  
Idaho Falls, ID 83404

RE: Idaho Surgicenter North, Provider #13C0001035

Dear Ms. Conilogue:

Based on the survey completed at Idaho Surgicenter North, on August 21, 2015, by our staff, we have determined Idaho Surgicenter North is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFR 416.41)** and **Infection Control (42 CFR 416.51)**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused these conditions to be unmet, substantially limit the capacity of Idaho Surgicenter North, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Condition for Coverage referenced above by submitting a written Credible Allegation of Compliance/Plan of Correction.

An acceptable Plan of Correction contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;

Charlene Woodland, Administrator  
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- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of each form.

**Such corrections must be achieved and compliance verified by this office, before October 5, 2015. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than September 25, 2015.**

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **September 17, 2015.**

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

We urge you to begin correction immediately.

If you have any questions regarding this letter or the enclosed reports, please contact me at (208) 334-6626, option 4.

Sincerely,

  
SUSAN COSTA  
Health Facility Surveyor  
Non-Long Term Care

  
NICOLE WISENOR  
Co-Supervisor  
Non-Long Term Care

SC/pmt

Enclosures

cc: Debra Ransom, R.N., R.H.I.T., Bureau Chief  
Lynnette Osias, CMS Region X Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/04/2015  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  13C0001035	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  08/21/2015
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NAME OF PROVIDER OR SUPPLIER  IDAHO SURGICENTER NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 3369 A MERLIN DRIVE IDAHO FALLS, ID 83404
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification survey of your ASC from 8/17/15 to 8/21/15. Surveyors conducting the recertification were:</p> <p>Susan Costa, RN, HFS, Team Leader Dennis Kelly, RN-BC, CHPN, HFS</p> <p>Acronyms used in this report include:</p> <p>AORN - Association of Peri-Operative Registered Nurses APIC - Association for Professionals in Infection Control and Epidemiology ASC - Ambulatory Surgical Center BI - Biological Indicator CDC - Centers for Disease Control CPR - Cardio Pulmonary Resuscitation CRNA - Certified Registered Nurse Anesthetist CST - Certified Surgical Technician H&amp;P - History and Physical HIPPA - Health Insurance Portability and Accountability Act IFU - Instructions for Use IV - Intravenous OR - Operating Room OSHA - Occupational Safety Health Administration PA - Perioperative Assistant QI - Quality Improvement RN - Registered Nurse</p>	Q 000	<p style="text-align: center;"><b>RECEIVED</b> <b>SEP 17 2015</b> <b>FACILITY STANDARDS</b></p>	
Q 040	<p>416.41 GOVERNING BODY AND MANAGEMENT</p> <p>The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing</p>	Q 040		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>C. Cmolegza</i>	TITLE <i>Administrator</i>	(X6) DATE <i>9-17-15</i>
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Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 040	<p>Continued From page 1</p> <p>the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.</p> <p>This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of medical records and ASC policies, it was determined the ASC failed to ensure the Governing Body developed, implemented, and monitored policies and programs necessary to ensure all patient needs were met. This resulted in the inability of the facility to ensure quality health care services were provided in a safe manner. Findings include:</p> <p>1. The ASC's personnel and credentialing records were reviewed. The records included documentation of employment at 2 separate ASCs. The other ASC, although it was distinctly separate, with a separate Medicare number, had a similar name and the Administrator worked for both facilities in the same capacity.</p> <p>During an interview on 8/20/15 beginning at 5:15 PM, the Administrator confirmed the personnel records for both ASCs were shared in a single binder. She stated that, as Administrator at both ASCs, she found it easier to maintain the files in that fashion.</p> <p>The personnel records were not accurate and complete, as follows:</p>	Q 040			

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Q 040	<p>Continued From page 2</p> <p>a. RN C was employed by the ASC from 12/11/14 to 4/01/15. Her personnel record did not include current competency validation, evidence of inservice attendance, or infection control inservices for the ASC. However, her personnel records were combined with another ASC, and inservice documentation was included the letterhead for the other ASC.</p> <p>During an interview on 8/20/15 beginning at 5:15 PM, the Administrator stated that if the personnel records were separated for each ASC, RN C's personnel record would not be complete.</p> <p>b. The personnel record for CST B was reviewed, and dates of employment was documented from 4/18/14 to present. Her record included a competency evaluation, dated 4/18/14 and signed by the Administrator, but it was not signed by CST B.</p> <p>An "Orientation Checklist," signed by the Administrator, documented the checklist was completed and signed on 4/17/14, a day before CST B started employment.</p> <p>During an interview on 8/20/15 beginning at 5:15 PM, the Administrator reviewed CST B's personnel record. She stated the entire record reflected documentation of CST B's employment at the other ASC. She confirmed that if the personnel records were separated for each ASC, CST B's personnel record would not be complete.</p> <p>c. RN A was employed by the ASC from 4/28/15 to 7/01/15. Her personnel record included competency evaluations, procedural and equipment operational checklists, HIPAA compliance worksheets, and orientation</p>	Q 040		

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Q 040	<p>Continued From page 3 checklists. However, all the forms were blank.</p> <p>The Administrator was interviewed on 8/20/15 beginning at 5:15 PM, and confirmed RN A's personnel record was incomplete.</p> <p>The ASC failed to ensure complete, accurate personnel records were maintained.</p> <p>2. During the Entrance conference on 8/17/15, PA A identified her position at the ASC as Director of Operations and Perioperative Assistant. However, the personnel record for PAA included job descriptions for Surgical Scrub, Perioperative Assistant, and Circulator.</p> <p>a. The position description in PAA's record for "Surgical Scrub" stated she was "To assist the podiatrist directly in surgery by performing the technical functions delegated by the doctor as a member of the surgical team that works in the sterile field and assists the surgeon."</p> <p>The qualifications for Surgical Scrub included, but were not limited to, "The scrub nurse is to be a certified surgical technician with the amount of continuing education required by the certification. The scrub nurse must also carry his/her own insurance."</p> <p>However, PAA's personnel record did not include documentation of certification for surgical technician or of her own insurance.</p> <p>b. The position description in PAA's personnel record for "Circulator" stated she "Provides patient care as the circulator in the operating room in accordance with Nursing Policy and Procedure Manual in order to provide the highest</p>	Q 040		

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Q 040	<p>Continued From page 4</p> <p>quality of care in the safest environment possible."</p> <p>The qualifications for Circulator included, but were not limited to, "Must be a registered Nurse and hold a current license in the State of Idaho, or be a trained technician with oversight by the registered nurse."</p> <p>PAA's record did not include documentation she was a RN in the state of Idaho, or of technician training. PAA's record did not include documentation of certification, licensure, or other medical training.</p> <p>During an interview on 8/20/15 beginning at 5:15 PM, the Administrator reviewed PAA's personnel record. She confirmed PAA did not have insurance coverage, medical training, or licensure for the positions of Surgical Scrub and Circulator. She stated PAA worked in the areas as a relief when the ASC needed coverage.</p> <p>The ASC failed to ensure staff were employed in accordance with established job description qualifications.</p> <p>3. Refer to Q161 as it relates to the Governing Body's failure to ensure the ASC developed, implemented and monitored policies and procedures necessary to ensure patient records were maintained in a secure manner. -</p> <p>4. Refer to Q181 as it relates to the Governing Body's failure to ensure drugs were stored, utilized, monitored and disposed of in accordance with accepted standards of practice.</p> <p>5. Refer to Q225 as it relates to the Governing</p>	Q 040			

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Q 040	Continued From page 5 Body's failure to ensure a procedure for documenting the existence, submission, investigation, and disposition of grievances had been developed and implemented.  6. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented and monitored necessary to minimize infections and communicable diseases.  The cumulative effect of these systemic deficient practices resulted in the inability of the facility to furnish patient care in a manner which ensured patients' health and safety were protected and patient rights were upheld.	Q 040			
Q 161	416.47(a) ORGANIZATION  The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.  This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to develop, implement and monitor policies and procedures necessary to ensure patient records were maintained secure manner. This failure directly impacted 2 of 2 patients (#12 and #13) whose surgical procedures were observed, and had the potential to impact all patients receiving care at the ASC. This resulted in the potential for protected patient health information to be accessed by unauthorized individuals. Findings include:	Q 161			

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Q 161	Continued From page 6 On 8/21/15 beginning at 7:15 AM, Patient #12's record was reviewed in preparation for observation of her a surgical procedure. The record did not include an H&P.  On 8/21/15 at approximately 7:30 AM, the RN arrived. She brought a folder with the initials of the ASC written on the outside. Inside the folder were the H&Ps for Patient #12 and Patient #13.  When asked, on 8/21/15 at approximately 7:30 AM, the RN stated she took the original H&P from each patient record home. She stated she would speak with the patients the night before the procedure, and document her pre-procedural phone assessment. The RN confirmed she removed patient health information from the ASC and stated she kept the information in the folder when she was not reviewing the information. When asked, the RN stated the ASC did not have a policy or process which addressed how patient protected health information would be kept secure during pre-procedural assessments and phone calls.  The ASC failed to develop, implement and monitor policies and procedures necessary to ensure patient records were maintained secure manner.	Q 161			
Q 181	416.48(a) ADMINISTRATION OF DRUGS  Drugs must be prepared and administered according to established policies and acceptable standards of practice.	Q 181			

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Q 181	<p>Continued From page 7</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review, and staff interview, it was determined the facility failed to develop a comprehensive system necessary to ensure drugs and biologicals were stored, utilized, monitored and disposed of in accordance with accepted standards of practice for all patients receiving medications at the ASC. This resulted in the potential for patients to receive drugs in an unsafe and ineffective manner. Findings include:</p> <p>1. A tour of the facility was conducted on 8/20/15 at 9:00 AM with the PA, who unlocked the crash cart, anesthesia cart, the controlled substances cabinet, and combination safe.</p> <p>However, the facility's Controlled Substances policy, dated 10/23/13, stated "...controlled substances shall be maintained in a double-locked cabinet in the nurse's station..." and "...the keys will be maintained by the anesthesia team member or by the registered nurse." It also stated "keys to the anesthesia cart will be maintained by the anesthesia team member."</p> <p>The Administrator was interviewed on 8/20/15 at 3:00 PM. She confirmed the PA had keys and access to the ASC's crash cart, anesthesia cart and controlled substances cabinet and combination safe.</p> <p>The facility failed to ensure medications were kept secure in accordance with facility policy.</p> <p>2. The Controlled Substances policy, dated 10/23/13, stated "DEA controlled drugs administered for use or disposed of shall be</p>	Q 181			

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Q 181	<p>Continued From page 8</p> <p>recorded in compliance with state and federal regulations." It also stated "each controlled substance shall have its own log page in the controlled substance log."</p> <p>A tour of the facility was conducted on 8/20/15 at 9:00 AM with the PA, who unlocked the controlled substances cabinet and safe. The following discrepancies were noted:</p> <ul style="list-style-type: none"> <li>- The controlled substances log stated propofol 50 ml had 16 remaining, however, the count was 15</li> <li>- The proof of use sheet stated versed 2mg/ml was in the controlled substances safe, however, versed 1mg/ml was in the safe.</li> </ul> <p>The PA was interviewed on 8/20/15 at 9:15 AM. She stated one bottle of propofol 50 ml was sold to another ASC and confirmed the controlled substance log and the count did not reconcile. She also stated there was no documentation of the sale of propofol to another ASC in the log. She stated she did not prepare the controlled substance logs, therefore, she did not know why the dosage of versed was incorrect.</p> <p>The RN was interviewed on 8/21/15 at 10:00 AM. She confirmed the count of propofol was incorrect. She also stated she did not know why the versed dosage in the controlled substance log did not match the versed in the safe. She stated in may have been an entry error when the log was created on 6/19/15.</p> <p>The ASC did not accurately record the use and disposal of controlled substances.</p> <p>3. The Crash Cart Contents policy, dated</p>	Q 181			

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Q 181	<p>Continued From page 9</p> <p>10/23/13, stated the RN or PA were responsible for checking for outdated medication, removing expired drugs and reordering immediately before the next scheduled surgery day.</p> <p>The Storage of Medications Policy, dated 11/02/13, stated "...the RN and CRNA shall inspect all medications for expiration dates, and shall remove those medications which are or will soon expire; he/she shall provide a written quarterly report of those medications he/she has removed from patient use."</p> <p>A tour of the facility was conducted on 8/20/15 at 9:00 AM with the PA, who unlocked the crash cart and the anesthesia cart. Medications and biologicals were expired, as follows:</p> <p>a. The crash cart contained the following expired medications:</p> <ul style="list-style-type: none"> <li>- 50% Dextrose, with an expiration date of 6/15.</li> <li>- Epinephrine 1:10,000, with an expiration date of 12/01/14.</li> <li>- Epinephrine 1:1000, with an expiration date of 12/01/14.</li> <li>- Lidocaine 2 gm per mixed IV 500 cc, with an expiration date of 3/15.</li> <li>- Nitrostat tabs, with an expiration date of 6/15.</li> <li>- Sterile H2O 50 ml for injection, with an expiration date of 4/15.</li> <li>- MgSO4 10 ml, with an expiration date of 11/13</li> <li>- Pitressin 20u/ml, with an expiration date of 1/15.</li> </ul> <p>b. The anesthesia cart contained the following expired medications:</p> <ul style="list-style-type: none"> <li>- Lidocaine with epinephrine 1% 1:100,000 50 ml, with an expiration date of 6/15.</li> </ul>	Q 181			

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Q 181	<p>Continued From page 10</p> <ul style="list-style-type: none"> <li>- 1 box of 10 ammonia ampules, with an expiration date of 4/09.</li> <li>- 1 box of 12 ammonia ampules, with no expiration date noted.</li> </ul> <p>The Administrator was interviewed on 8/20/15 at 3:00 PM. She confirmed the drugs were expired and stated no order had been made to replace the expired drugs. She also stated the ASC procedure for ordering replacement medications was for the RN to notify the PA.</p> <p>The RN was interviewed on 8/21/15 at 10:00 AM. She confirmed she inspected the crash cart, documented the expired drugs on the crash cart drugs list and notified the PA to order medications. She stated the expired drugs were not removed from the crash cart and replacement drugs were not ordered.</p> <p>The PA was interviewed on 8/20/15. She stated she had the list of expired drugs and had made attempts to order, but the vendors did not sell the drugs in units small enough to restock the crash cart. She confirmed the most recent communication to vendors to replace expired drugs was 9/09/14.</p> <p>The physician owner was interviewed on 8/21/15 at 11:00 AM. He confirmed the ASC held quarterly QI and Governing Body meetings but did not include a discussion of expired medications. He also stated he did not know the medications were expired.</p> <p>The facility failed to ensure expired medications were removed.</p>	Q 181			
Q 225	416.50(d)(4),(5), & (6) SUBMISSION AND	Q 225			

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Q 225	<p>Continued From page 11 <b>INVESTIGATION OF GRIEVANCES</b></p> <p>The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:</p> <p>(1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>(2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>(3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies, patient rights information, and complaint logs, it was determined the ASC failed to ensure a procedure for documenting the existence, submission, investigation, and disposition of grievances had been developed and implemented. This failure directly impacted 1 of 1 patients (#10) whose complaint was reviewed and had the potential to impact all patients receiving care at the facility. This resulted in a lack of a clear system for patients to voice grievances and for staff to respond to those</p>	Q 225			

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Q 225	Continued From page 12 grievances. Findings include:  The ASC policy titled "Written Complaints," dated 10/23/15, stated "...patient care surveys will be given to all patients who receive services...returned surveys will be submitted to the Director of Operations upon receipt... [and]...complaints will be documented with the decided process to correct the complaint." The policy also stated patients "...will be notified of the process by phone or in writing." Additionally, the ASC's post-operative questionnaire stated "every effort will be made to investigate your complaint."  The ASC's complaint log 1/01/14 to 8/20/15 was reviewed and included one post-operative patient questionnaire that documented a complaint/grievance. The post-operative questionnaire stated the nurse "kept poking and poking and blew my vein trying to get the IV line in" for a procedure completed on 6/19/15.  The Administrator was interviewed on 8/20/15 at 3:00 PM. She stated she was unaware of the complaint. She reviewed the complaint and was able to identify Patient #10 as the author. She stated she was unsure whether it was a complaint/grievance and unsure if she needed to pursue it further. The Administrator confirmed that all complaints were her responsibility to follow-up on but that there were so few, she was unsure of the process. She confirmed there was no investigation or follow-up to the complaint.  The ASC did not identify, investigate or respond to a grievance.	Q 225			
Q 240	416.51 INFECTION CONTROL	Q 240			

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Q 240	Continued From page 13 The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.  This CONDITION is not met as evidenced by: Based on observation, ASC policy review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented, and monitored for all facility staff and patients receiving care at the facility. This resulted in the the potential for increased risk of patient infections. Findings include:  1. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice.  2. Refer to Q242 as it relates to the ASC's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained.  3. Refer to Q243 as it relates to the ASC's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.  The cumulative effect of these systemic deficient practices resulted in the inability of the facility to ensure patient risk of infections and communicable diseases was minimized.	Q 240			
Q 241	416.51(a) SANITARY ENVIRONMENT  The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable	Q 241			

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Q 241	<p>Continued From page 14 standards of practice.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, policy review and record review, it was determined the facility failed to maintain a sanitary and functional environment. This failure directly impacted 1 of 1 patients (#12) whose procedure was observed and had the potential to impact all patients receiving care at the facility. This resulted in the potential for infections to occur and for expired supplies to be used. Findings include:</p> <p>The ASC policy Infection Control Plan, revised 10/2/2013, stated the ASC's infection control program was established to comply with the approved regulatory guidelines chosen by the Governing Body. Governing Body approved guidelines included the following:</p> <ul style="list-style-type: none"> <li>- AORN,</li> <li>- APIC,</li> <li>- OSHA,</li> <li>- CDC,</li> <li>- CMS,</li> <li>- State Health Department: Idaho Department of Health.</li> </ul> <p>However, facility practices were not consistent with nationally recognized standards of practice, as follows:</p> <p>1. The ASC's environment and supplies were not consistent with nationally recognized standards of practice, as follows:</p> <p>a. AORN's recommended practices for traffic patterns state "...movement of personnel should be kept to a minimum while invasive procedures</p>	Q 241			

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Q 241	<p>Continued From page 15</p> <p>are in progress...[and]...in order to maintain critical environmental parameters such as a minimum of 15 total room air exchanges per hour, doors to the operating rooms should be closed." It also stated "air is a potential source of microorganisms that can contaminate surgical wounds."</p> <p>Patient #12 was a 66 year old female admitted to the ASC on 8/21/15 at 7:30 AM for a surgical correction of a bunion and a hammer toe on her right foot. Patient #12 was observed on 8/21/15 from 7:30 AM to 10:05 AM. Her surgical procedure was observed from 8:38 AM to 9:26 AM. During the observation, it was noted that the OR door remained open throughout the entire surgical procedure. Immediately outside the OR was a corridor that had multiple staff walking past the operating room.</p> <p>b. On 8/21/15 at 7:30 AM the OR was observed. An OR floor air vent was observed to create a current of air that was below a large plastic trash container. The trash container had a plastic bag in it, and the bag was moving with the air flow. The Mayo stand held an open, sterile patient prep setup. Next to the Mayo stand, the surgical instrument cart was open. Both sterile drapes on the Mayo stand and instrument cart were moving with the air currents that passed up and past the trash can.</p> <p>During an interview with the CST on 8/21/15 beginning at 11:15 AM, she confirmed the air flow from the floor vent. She stated it concerned her that the floor vent was a possible risk related to infection control.</p> <p>c. Instrument reprocessing was observed on</p>	Q 241			

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Q 241	<p>Continued From page 16</p> <p>8/21/15 beginning at 11:00 AM. The room in which the instruments were decontaminated, cleaned, and sterilized, included a counter between the autoclaves and the double sink. The counter area was approximately 2 feet wide. Decontamination, drying of instruments, and wrapping of instruments were all performed on the same counter.</p> <p>According to AORN 2015 Guidelines for Perioperative Practice, "Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled. Physical separation of decontamination areas from areas where clean items are handled minimizes the risk of cross-contamination." Additionally, "The sterile processing area should have a distance of 4 feet between the instrument washing sink and the area where the instruments are prepared for sterilization."</p> <p>During an interview on 8/21/15 beginning at 11:15 AM, the CST, who was also the Administrator confirmed the decontamination area was also the same counter space used for wrapping of clean instruments for sterilization. She stated the room was very small, and possibly an autoclave could be moved over, or one placed on the clinic side of the building to free up more room.</p> <p>d. During a tour of the ASC on 8/20/15 beginning at 9:00 AM, a rechargeable hair clipping device was noted in the admission and recovery room area for the surgical patients. The device was identified by the PA as a beard and mustache trimmer, and confirmed it was for home use, not multi-patient or medical use. She stated the device was not used very often, and the ASC was looking into securing a new one. She stated the</p>	Q 241		

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Q 241	<p>Continued From page 17 device was wiped down with a disinfectant after it was used.</p> <p>QI meeting minutes for 3/20/15 were reviewed. The minutes noted "We need a new rechargeable razor for pre-operative shaves. [Name of Administrator] will look into [brand name of item]."</p> <p>However, as of the date of the survey, a new razor had not been secured.</p> <p>e. On 8/20/15, beginning at 9:00 AM during a tour of the ASC, cleaning supplies were observed in the OR, which were were expired and/or not labeled adequately, as follows:</p> <ul style="list-style-type: none"> <li>- Chlorhexidine 4% solution, partially full, expiration date 5/2014.</li> <li>- Spray bottle, labeled "Clorox," undated, dry and flaky around top of spray outlet.</li> <li>- Spray bottle, labeled "Lysol," undated.</li> <li>- Spray bottle, labeled "Maxima," undated.</li> <li>- Personal bottle of hand lotion, undated, and not antibacterial.</li> </ul> <p>The PA was present during the ASC tour and she confirmed the items were expired or not labeled adequately. She removed the items from the OR at that time.</p> <p>The ASC failed to ensure a functional, sanitary environment and supplies were provided for surgical patients.</p> <p>2. Instrument reprocessing was observed on 8/21/15 beginning at 11:00 AM. Reprocessing was not completed in a manner consistent with nationally recognized standards of practice, as follows:</p>	Q 241			

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Q 241	<p>Continued From page 18</p> <p>a. The CST was observed to place a plastic tub in each side of the double sink. She then used a name brand household dishwashing liquid to make a foamy bath for cleaning of the instruments.</p> <p>According to AORN 2015 Guidelines for Perioperative Practice, "The instruments should be submerged for cleaning in a solution of water and detergent intended for cleaning surgical instruments. The detergent should be compatible with the device to be cleaned and used at the concentration and temperature specified"</p> <p>When asked, during the observation on 8/21/15 beginning at 11:00 AM, the CST stated the ASC had an ultrasonic cleaner, but several years ago it stopped working, so she cleaned the instruments manually. Additionally, the CST stated she did not scrub all the instruments. If they were open, yet unused, she just rinsed them.</p> <p>However, the AORN 2015 Guidelines for Perioperative Practice, stated "All instruments opened onto the sterile field in the operating or procedure room should be cleaned and decontaminated whether or not they have been used."</p> <p>The facility failed to ensure all instruments were cleaned appropriately.</p> <p>b. A wire brush was used to scrub the instruments, then they were placed in the tub that had tap water in the other side of the sink. The water for rinsing the instruments was not filtered or otherwise adapted for rinsing of instruments.</p>	Q 241			

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Q 241	<p>Continued From page 19</p> <p>During the observation of the cleaning of surgical instruments, the CST stated she used the wire brush because the ASC did not have a functioning ultrasound.</p> <p>According to AORN 2015 Guidelines for Perioperative Practice, "Abrasive devices and products should not be used to clean instruments unless their use is specified. Abrasive devices can cause permanent damage to instrument surfaces and can result in pitting."</p> <p>The AORN 2015 Guidelines for Perioperative Practice also stated, "The decontamination area should be stocked with the accessories and supplies needed to clean and decontaminate instruments. Supplies should include enzymatic and nonenzymatic detergent, a source of treated water [e.g. deionized, reverse osmosis, filtered]...Impurities in untreated water can leave residues on instruments that may lead to corrosion, pitting, or staining. Untreated water can contain contaminants, including endotoxins, which can be deposited on instruments during the final rinse. Endotoxins are heat stable and may not be destroyed by subsequent steam sterilization."</p> <p>The ASC failed to ensure surgical instruments were decontaminated and prepared for sterilization according to current standards of practice.</p> <p>c. After the instruments were rinsed, the CST placed the instruments on a drying mat, then they were placed in a ventilated tray. She placed the tray on a shelf above the autoclaves, and stated the instruments would remain there until the next surgery date, approximately two weeks</p>	Q 241			

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Q 241	<p>Continued From page 20</p> <p>away. The CST confirmed the instruments were only decontaminated, and an enzymatic or other disinfection solution was not used to ensure bacterial growth did not occur during the lapse of time from cleaning of the instruments until they were sterilized.</p> <p>The ASC failed to ensure instruments were properly disinfected prior to sterilization.</p> <p>d. During the observation, multiple bundles of single use, disposable, non woven, blue wraps were noted in the room. The CST stated she re-used the wraps after instruments were sterilized and opened. She stated she also used the disposable wraps from purchased surgical kits that the gowns were wrapped in. The CST was observed to wrap instruments with previously used single use, non woven wraps.</p> <p>According to AORN 2015 Guidelines for Perioperative Practice, "Wrapping materials labeled for single-use should be discarded after one sterilization cycle. Products labeled as single-use or disposable are intended for one use and are not intended to be reprocessed."</p> <p>The ASC failed to ensure single-use wraps were not re-used.</p> <p>e. After the instruments were decontaminated, the CST opened the suction canister that was used during a surgical case that had occurred earlier in the day. The canister contents were a pink cloudy liquid, which the CST stated was blood, irrigation solution, and possibly bone fragments. The contents of the suction canister was poured down the sink drain. The CST then used the household dishwashing liquid that was</p>	Q 241			

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Q 241	<p>Continued From page 21</p> <p>used when decontaminating the instruments to wash out the canister. She used a plastic brush with a long handle to scrub inside the canister, then the brush was placed on the counter between the sink and the wall.</p> <p>According to Idaho Department of Environmental Quality, infectious medical waste should be disinfected before disposal in a properly permitted landfill. Additionally, the infectious medical waste must be contained in disposable containers that are moisture resistant and strong enough to prevent leakage.</p> <p>The ASC failed to ensure medical waste was disposed of properly.</p> <p>f. During the observation on 8/21/15 beginning at 11:00 AM, the CST stated the fan and the printer for Autoclave 2 was not working, and had not been working for more than a year. (Autoclave #1 was an older model and did not have a printer). She stated she was told the fan was not critical to the autoclave function.</p> <p>Governing Body meeting minutes, dated 11/14/14 and 3/20/15, included information related to the fan and printer. The minutes stated an inspection in November revealed that the cooling fan of the back of the autoclave was not working. The minutes noted that it was not necessary to have a properly and safely operating autoclave. The minutes noted the autoclave printer was taken to be repaired. The meeting minutes for 3/20/15 included the same information. There was no further documentation provided by the ASC to indicate further efforts were made to repair the autoclave.</p>	Q 241			

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Q 241	<p>Continued From page 22</p> <p>Further, the autoclave sterilizer log was reviewed, the last load that was recorded by the printer was 6/27/14. The printed record included the load number, type of load (such as pouches, bare instruments, implacable devices), temperature range, sterilizing duration and pressure, and total processing time.</p> <p>g. The sterilizer log was reviewed. The log included entries written in by hand and did not include the detail the printed record provided. The entries were dated from 7/11/14 to 8/07/15. The handwritten entries included the type of load (contents), which sterilizer was used, load number, and staff initials who processed the load.</p> <p>According to AORN 2015 Guidelines for Perioperative Practice, "Information should be recorded from each sterilization cycle. Recording of physical data should be used for all sterilization methods to ascertain that sterilization systems function within manufacturers' specifications, and should include:</p> <ul style="list-style-type: none"> <li>- identification of the sterilizer,</li> <li>- type of sterilizer and cycle used,</li> <li>- load control number,</li> <li>- load contents,</li> <li>- critical parameters for the specific sterilization methodology, (e.g., exposure time, temperature for steam sterilization),</li> <li>- operator's name,</li> <li>- results of sterilization process monitoring (i.e., biological, chemical, physical). ***Is this a quote?"</li> </ul> <p>The ASC failed to ensure sterilization logs included sufficient information.</p>	Q 241			

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Q 241	<p>Continued From page 23</p> <p>h. The BI logs were reviewed with the CST on 8/21/15 at 8:00 AM. Documentation was noted when the indicators were used during sterilization monitoring, and when they were sent through with biological implants.</p> <p>The CST stated that the morning of each surgery day in the ASC, a BI was run through the sterilizer. She stated the indicator and the control would then be placed in the incubator. The CST stated that at the end of the work day, the Office Manager would unplug the incubator, take it home (approximately 30 miles away), and plug the incubator in at her home. She would then obtain and record the results for the control and sterilized BI samples. The CST confirmed the log indicated the samples were recorded as out of the incubator ranging from 34 to 37 hours. She confirmed the incubator temperature was not maintained at a constant temperature level during the period it was transported to the Office Manager's home.</p> <p>The CST also stated the BI log for implants included documentation of when the implant and BI was sterilized, and when the implant was used. She stated the ASC policy for implants are that they are always sterilized and the results of the BI would be obtained before the scheduled implant procedure. However, the policy for securing a BI result before the implant was used was not consistently implemented, as follows:</p> <ul style="list-style-type: none"> <li>- Load #2, Autoclave #2, implant- screws and BI sterilized on 12/26/14, results of BI on 12/27/14. Implants placed on 12/26/14, before the results were obtained.</li> <li>- Load #2, Autoclave #1, implant- screws and BI</li> </ul>	Q 241			

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Q 241	<p>Continued From page 24</p> <p>sterilized on 1/09/15, results of BI on 1/10/15. Implants placed on 1/09/15, before the results were obtained.</p> <p>- Load #2, Autoclave #2, implant- screws and BI sterilized on 1/09/15, results of BI on 1/10/15. Implants placed on 1/09/15, before the results were obtained.</p> <p>- The autoclave and load number were not documented. Implant- screws and BI sterilized on 3/13/15, results of BI on 3/14/15. Implants placed on 3/13/15, before the results were obtained.</p> <p>The CST reviewed the log and confirmed the policy was not followed and implants occurred before the BI results were obtained.</p> <p>i. An ASC policy titled "Sterilization Records," revised 10/02/13, stated "The steam sterilizer is tested a minimum of once a week with Attest Biologic Indicator."</p> <p>However, the BI log sheet documented BI was tested on only 4 occasions (on 6/19/15, 6/26/15, 7/31/15, and 8/07/15) during the previous 3 month period (7/2015 - 8/2015).</p> <p>During an interview with the CST on 8/21/15 beginning at 8:00 AM, she stated the clinic portion of the practice shared the use of both ASC autoclaves, and confirmed the BI testing was not performed at the weekly frequency as detailed in the policy.</p> <p>The ASC failed to ensure reprocessing was completed in a manner consistent with nationally recognized standards of practice.</p>	Q 241		

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Q 241	Continued From page 25  3. Patient linens, washable cleaning items such as mop heads, and staff scrub clothes were laundered at home by an employee. The Infection Control Manual included a policy titled "Laundry," revised 10/02/13. It stated the laundering of scrubs, linens, and patient gowns were done by the facility. It also stated additional items laundered by the facility were mop heads, utility towels, and nurse's caps.  The Infection Control Manual included a letter from PAA, dated 1/03/13, and addressed "To whom it May Concern." The letter was as follows:  "The following is a statement of waiver concerning the laundry handling for Idaho Surgicenter North, LLC. I, [ PAA] have taken on the responsibility for taking care of the soiled laundry off site by my own choice. The following is the method of care for ISCN linens..." The laundry care instructions included the following:  - "The laundry is pre-treated on site per policy."  - "The laundry is handled while wearing gloves and removed from the building in clear plastic garbage liners from the soiled laundry containers. These sacks are knotted and place [sic] into the trunk of my car at the end of the day."  - "The temperature of my water heater is turned up to 165 degrees on Friday night. Washing of the laundry is started on Saturday with the washing and drying done per the policy in the infection control manual for IDAHO [sic] Surgicenter North. (Hot wash water with a warm rinse- ¼ C detergent and ¼ C bleach) No fabric softeners are used in the process."	Q 241			

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Q 241	Continued From page 26  - "The laundry is done in separate loads according to the type and color of the fabric."  - "The laundry is folded on a table and placed into clean black garbage sacks. The sacks are knotted and placed into the back seat of my car."  - "The sacks are carried into IDAHO [sic] Surgicenter North and stores [sic] in th [sic] appropriate cupboards."  According to the 2015 Edition AORN Guidelines for Perioperative Practice, "All individuals who enter the semi-restricted and restricted areas should wear scrub attire that has been laundered at a health care-accredited laundry facility or disposable scrub attire provided by the facility and intended for use within the perioperative setting. Using health care accredited laundry facilities is recommended because they meet industry standards. Reusable scrub attire should be left at the health care facility for laundering."  During an interview on 8/21/15 beginning at 8:30 AM, PA A confirmed she took the items to her home for laundering. She stated she had contacted multiple laundry providers in the community, and met with difficulties such as one company wanted to use their own linens, and the other companies that would not abide with the temperature controls.  The ASC failed to ensure laundry was cleaned and stored in accordance with nationally recognized standards of practice.	Q 241			
Q 242	416.51(b) INFECTION CONTROL PROGRAM	Q 242			

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Q 242	<p>Continued From page 27</p> <p>The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>This STANDARD is not met as evidenced by: Based on interview and review of infection control documentation, it was determined the agency failed to ensure that ongoing surveillance was conducted within the ASC to ensure adherence to infection control policies. This had the potential to result in patient infection due to poor infection control practices. Findings include:</p> <p>1. The Infection Control Policy, revised 10/02/13, stated surveillance activities would include ongoing monitoring of patients, visitors, and staff, as well as the analysis of data to detect changes or infection trends.</p> <p>During an interview, with the RN Infection Control Officer on 8/21/15 at 12:00 PM., she stated surveillance activities included hand washing monitoring. However, she stated the last monitoring occurred in October, 2014.</p> <p>2. The Infection Control Policy, stated patients would be seen within 48 hours after surgery for assessment. However, the ASC performed surgery on Fridays, and the practice was closed until Monday mornings. This did not provide for a post surgical assessment to occur within 48 hours.</p>	Q 242			

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Q 242	Continued From page 28 The policy was reviewed with the RN Infection Control Officer during an interview on 8/21/15 at 12:00 PM. The Infection Control Officer confirmed the 48 hour post surgical assessment did not occur.  3. The Infection Control Policy stated an annual review and revision of infection control policies and procedures would occur.  However, during an interview, with the RN Infection Control Officer on 8/21/15 at 12:00 PM., she was unable to provide evidence of an annual review.  The ASC failed to ensure a comprehensive ongoing infection control program was implemented and maintained.	Q 242		
Q 243	416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION  The program is - Under the direction of a designated and qualified professional who has training in infection control.  This STANDARD is not met as evidenced by: Based on record review and staff interviews, it was determined the ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control for all staff and all patients receiving care at the facility. This prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings	Q 243		

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Q 243	<p>Continued From page 29 include:</p> <p>The Infection Control Policy, revised 10/02/13, included the name of the Infection Control Officer. It stated 15% of her time was dedicated to oversight of the Infection Control Program. Additionally, the policy noted the Infection Control Officer would receive specific training in infection control.</p> <p>Upon review of the RN Infection Control Officer's personnel record, there was no indication she received additional or specific training related to infection control. Her record matched the other employees personnel records with the same inservice attendance information.</p> <p>During an interview with the RN Infection Control Officer on 8/21/15 at 12:00 PM, she confirmed she did not have specific infection control training as the policy stated. She stated she also worked at a large hospital in the community, and had received infection control training there, but stated it was the general education provided to all nursing staff. Her personnel record did not include additional educational documentation.</p> <p>The facility failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.</p>	Q 243			

**Q 040 Governing Body and Management****FACILITY STANDARDS**

Dr. Quinton (the Medical Director) called a Special Governing Body Meeting on 08-22-15 to discuss the findings presented at the closing interview with the team from the Bureau of Facility Standards and address these issues. Minutes are attached.

Governing Body convened again on 09-11-15 to follow up with assignments and tasks delegated to personnel on 08-22-15. These minutes are also attached.

1. Separate Personnel and Credentialing Records were created for the employees that had combined records from another facility within their Personnel records. This constitutes complete and separate personnel records for all employees at ISCNorth. All training, competencies, job descriptions, orientation checklists, etc. have been updated. The separation of files was completed on 08-28-15 by Charlene Conilogue, Admin. The creation of separate files was a good thing. It will ensure accuracy and complete personnel files for all employees of Idaho SurgiCenter North. Appropriate training will ensure that staff is trained in order to provide the best care for patients.

a. RN C was terminated April 1, 2015 and a new file was not created for her.

b. On 08-24-15, Charlene Conilogue held special training and orientation meeting for CST B whose file had documentation of training from a different facility. Charlene Conilogue CST, CFA performed this training at ISCNorth and oversaw her orientation and competency training as a senior staff member qualified to do so. It is contained in CST B's Personnel File. This staff member has signed all of her appropriate documentation.

c. RN A had an incomplete file as documentation of orientation had not been kept current with oriented skills by her supervisor. She was in training and had worked a total of 3 days when she was terminated. Our policy stated that training would last a total of 1 week not to exceed 30 hours before she would be allowed to work without supervision. The Governing Body amended the verbiage in the 2015 Personnel Manual to read, *"The orientation will last a minimum of 5 days and a maximum of 30 hours; will be documented by supervisor throughout orientation; will not be complete until the employee is able to fully function on his/her own. The orientation of new employees relative to their specific position at the surgery center will vary somewhat with the position, level of training, and experience of the employee. The supervisor conducting the orientation is responsible for determining the overall content and depth of the orientation. The minimum orientation will include reviews of: Position description; Patient rights information; Applicable ISCNorth Policy and Procedures; Infection control and aseptic techniques; Completion of applicable employee orientation forms. The completed orientation forms will be placed in the employee's personnel file."*

2. The staff referred to below have had changes made to their personnel files to include job descriptions and competencies appropriate to their responsibilities at Idaho SurgiCenter North. This documentation has been added to the personnel manual dated 08-22-15. Governing Body met on 09-11-15 and approved this manual with the aforementioned changes. Charlene Conilogue, Admin made the Personnel Manual updates on 08-22-15.

a. Our Personnel Policy Manual has been updated to indicate that certification or licensing is not necessary for a "relief" tech. The policy has also been updated to exclude phrasing for carrying insurance. As of 2002, PA A has not been used as a "relief" tech so her file doesn't contain a current job description for this position.

b. PA A's Personnel File has been updated to include a position description for a "relief" or "fill-in" operating room circulator. Our Personnel Policy Manual has been updated to indicate that RN licensing and ACLS is not necessary for a "relief" circulator. This position description and competency will be found in each employee's file if they are to be used as a relief circulator. Teri Fry, RN completed competencies for these staff members on 08-25-15.

3. On 9-11-15 at a special meeting, Governing Body added to Medical Records Policy Manual the way that patient information will be used for the pre-procedural phone assessment and for any other patient records used for assessments and reviews. Electronic records may be used in lieu of physical records. If copies are made, they are not to be retained, but returned to the ASC and shredded after use. This policy is in Idaho SurgiCenter North's Medical Records Policy Manual. Charlene Conilogue made these changes to the manual on 09-14-15, after Governing Body made the rule on 9-11-15.

4. On 08-22-15, a special meeting was called by Dr. Quinton and the Governing Body convened. It was evident from the statements taken by the team that the staff had failed to communicate the seriousness of the expired crash cart drugs to the Governing Body/Medical Director. It was on the agenda for several months, but no administrative action had been taken to ensure that crash cart drugs were replaced upon expiration. Dr. Quinton appointed Charlene Conilogue to be the staff member with authorization to order necessary crash cart drugs going forward. She will get his approval before ordering drugs. Governing Body also ruled that we will order drugs no less than 30 days before expiration. The narcotic key has been moved and secured; only Dr. Quinton and Teri Fry, RN are privy to how to access it. Teri Fry RN will continue to inventory the crash cart and when drugs are expired, she will "waste" them with the Anesthesia member or Dr. Quinton as is listed in our policy. Expired drugs will not be allowed to remain on the premises of Idaho SurgiCenter North. These changes will ensure that patients are receiving services at a facility that is equipped to deal with emergencies in a safe and practical manner according to rules and regulations set forth by CMS. We desire to provide such services to patients and will continue to be vigilant in auditing practices relating to crash cart contents and narcotic storage. These practices will improve the way that we provide quality service to patients and safeguard employees. Changes to these policies were made to the Nursing Manual on 09-15-15 by Charlene Conilogue, Administrator.

5. We addressed the negative comment on the survey per our Grievance Policy dated 2014 as a grievance however we failed to do it within the 10 days of receiving it because of the lack of surgery and no one being in the facility to address it. In the future, the Director of Operations, Toiny Schneider will forward all surveys to the Administrators office for evaluation per our policy. We did however address this complaint as our policy dictates which was at our next regularly held Governing Body Meeting on 08-20-15. Even though this was not a grievance and the grievance officer was not contacted by the patient as per instructed, we addressed it as a grievance. A Grievance Report was completed by the staff member familiar with the case (Teri Fry, RN) which was presented to the Governing Body. Although the offending staff member had since been discharged, it was decided that we would send the patient a letter thanking her for her attention to the matter. The letter was written by Charlene Conilogue, approved by the Governing Body on 09-11-15 and sent to her the same day. No response has been

noted as of this date. By responding within the specified time frame set forth in our policy regarding complaints and grievances, we will be able to address patient concerns in a timely manner, resolving concerns and improving relationships with patients and staff. This will provide information for improvement as we strive for ways to make patient experiences safer and more positive.

6. Governing Body addressed the failure to comply with Idaho SurgiCenter North policies on Infection Control by approving a budget and agreeing to oversee and monitor practices pertaining to staff participation in programs and in-services that will improve Infection Control practices and minimize infections and communicable diseases. The Infection Control Officer assigned Charlene Conilogue Administrator the task of training staff on Instrument Sterilization and Use of Biological and Chemical Indicators per the policy stated in these responses. The training was completed on 09-11-15 and is documented in Employee files as well as the In-service binder. Teri Fry is pursuing further education for Infection Control with Medline University. She will have at least 4 hours of training in place by 09-24-15 and complete 1 credit hour of training monthly thereafter. All staff will be trained quarterly on Infection Control issues at our regular QI meeting and be expected to adhere to strict laundry and instrument sterilization practices. Ms. Fry will arrange for this training with approval from Governing Body. By making these changes we hope to achieve our goal of improving practices that will enhance safety and improve outcomes for our patients.

#### **Q 161 416.47 (a) ORGANIZATION**

Governing Body added to Medical Records Policy Manual the way that patient information will be used for the pre-procedural phone assessment and for any other patient records used for assessments and reviews. Electronic records may be used in lieu of physical records. They are not to be retained, but returned to the facility and shredded after use. This policy is in Idaho SurgiCenter North's Medical Records Policy Manual. Charlene Conilogue made these changes to the manual on 09-14-15, after Governing Body made the rule on 9-11-15.

#### **Q 181: Administration of Drugs**

1. On 08-22-15, at the Special Governing Body Meeting, it was ruled that we will strictly adhere to our policy of safeguarding the narcotic and anesthesia cart keys. The key has been moved to remain in an undisclosed location. Dr. Quinton and Teri Fry RN are the only staff members with access or knowledge of the location of the narcotic cupboard key. Per our policy, the RN will be the individual responsible for the narcotic cupboard key on surgery days and will carry it on her person. The anesthesia cart key is locked inside the narcotic cupboard and will be released to the CRNA upon his arrival. The CRNA will continue to keep the anesthesia cart locked between cases and will keep the anesthesia cart key upon his person until which time it will be locked in the narcotic cupboard by the RN. Keeping the keys safeguarded will ensure that drugs don't fall into the wrong hands. It will provide for employee safety and accountability of drug storage and use. By strictly abiding by our policy, we will be able to provide a safer environment for patients receiving services at Idaho SurgiCenter North.

2. In order to address the issue of discrepancies in the controlled substance log, on 08-22-15, the Governing Body ruled that in order to keep acceptable records consistent with our policy, Dr. Quinton and another staff member chosen at his discretion will be the two qualified personnel accountable to count the drugs received, complete the narcotic form for future counting of the drugs and enter the

form into the narcotic log book. In Dr. Quinton's absence, the drugs will be signed for upon receipt by an available staff member and immediately locked in the O.R. suite. Upon Dr. Quinton's return, he will lock them in the narcotic cupboard with the hidden narcotic key. Dr. Quinton will assume all responsibility for these controlled substances. This will ensure that narcotics are safely counted and stored.

Expired drugs will be disposed of per our existing policy. They will be disposed of by the RN in the sharps container, turned back to the pharmacy, or wasted with (by) either the CRNA or the physician per our policy. This will be recorded in the Narcotic Log book by the RN. No expired drugs will be permitted in the ASC as ruled by the Governing Body. We will purchase drugs 30 days prior to their expiration dates as deemed necessary by the Governing Body. Charlene Conilogue Admin will be responsible to order these drugs upon approval from the Medical Director.

3. The RN responsible for disposing of expired drugs is Teri Fry, RN. She disposed of the expired drugs on 08-21-15 in a manner consistent with our policy.

3. a. All of the drugs listed on the 2567 have been replaced and were located in the crash cart before 09-10-15.

3. b. The expired ammonia ampules found in the anesthesia cart were disposed of on 08-21-15. The ammonia ampules located in the anesthesia cart that do not contain expiration dates were re-ordered on 09-16-15 after being advised by the pharmacist to dispose of them. Even though there is no expiration date on them, we will dispose of them when the new ampules are received. The Prescription Center of Idaho Falls ordered them for delivery on 09-18-15. They will notify Toiny Schneider, Director of Operations when they arrive and she will pick them up and leave them in the locked O.R. for either Dr. Quinton or Teri Fry, RN to place in the anesthesia cart. Toiny is also checking for the correct way to dispose of ammonia ampules and will follow those guidelines when she disposes of them.

Changes to the Controlled Substance policies have been updated by Charlene Conilogue, Administrator. The manual was approved and signed on 09-15-15.

#### **Q 225: Investigation of Grievances**

ISCNorth had a grievance procedure in place at the time of the survey on pages 29-32 of the 2014 Civil Rights Manual.

"Patient complaints will be brought before the Quality Improvement Committee at its regularly scheduled meeting unless a special meeting is necessary. The complaint will be reviewed and investigated. The process for correcting the complaint will be discussed, a study will be initiated if warranted, and resolutions passed to correct the complaint. Included in the Quality Improvement process for Patient Complaints will be the Medical Director, the Practice Administrator, and any other staff member who may be involved in the complaint. The committee for handling patient complaints will report its findings to the Governing Body.

Any patient may file a grievance under these procedures. It is against the law for Idaho SurgiCenter North to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.

#### **Written Complaints**

- Patient Care Surveys will be given to all patients who receive services at the Idaho SurgiCenter North. We will request that they return them in order for us

to monitor our performance as well as patient satisfaction. Patients will be encouraged to offer feedback without fear of retribution.

- The returned surveys will be submitted to the Practice Administrator upon receipt. For complaints or comments that need more immediate attention than the quarterly Quality Improvement meetings, the Practice Administrator will call an interim meeting of the Grievance Committee and any staff member who might be involved in the complaint.
- Complaints will be documented with the decided process to correct the complaint. It will be restudied as appropriate to guarantee quality care in all areas of the ambulatory surgery center and the supporting organization.
- The patient will be notified of the outcome of the process by phone or in writing within 10 business days of receiving the written complaint."

We addressed the negative comment on the survey as a grievance per Grievance Policy dated 2014. We failed to do it within the 10 days of receiving it because of the lack of surgery and no one being in the facility to address it. We did however address it as our policy dictates at our next regularly held Governing Body Meeting on 08-20-15. Even though this negative survey was submitted anonymously and the grievance officer was not contacted by the patient as per instructed, a Grievance Report was completed by the staff member familiar with the case (Teri Fry, RN) which was presented to the Governing Body on 08-20-15. Although the offending staff member had already been discharged, it was decided that we would send the patient a letter thanking her for her attention to the matter. The letter was written by Charlene Conilogue, approved by the Governing Body on 09-11-15 and sent to her the same day. No response has been noted as of this date. Copy of the letter is attached.

Governing Body held a special meeting on 09-11-15 and stressed that from this point forward when ANY negative comment is made on a survey, Toiny Schneider, Director of Operations will ensure that all surveys go directly to the Administrator, Charlene Conilogue for evaluation. We want patients to know that their input is valuable information for us as we strive to improve practices and create better and safer patient experiences. We will respond in this manner to not only official grievances, but any negative comment that may be returned on a survey. This manual has been reviewed and no changes were made.

#### **Q 240 416.51 INFECTION CONTROL/ Q241 416.51 (a) Sanitary Environment**

1. a. Our policy states that we will keep the door closed during cases in order to keep potential contamination to a minimum. At the Special Governing Body Meeting on 09-11-15, the governing body ruled that the door must be closed whenever sterile supplies are open in anticipation of a case or a patient is in the room to protect them from potential infection and protect privacy. This policy is part of our existing policy and we will commit to following it strictly in order to provide the protections to patients stated above. No changes were made to this existing policy on the door remaining closed, however the Governing Body enlisted the Infection Control Officer Teri Fry, RN, to monitor this practice and enforce compliance with our existing policy.

1. b. We have purchased vent covers that will direct the air flow away from the center of the room and prevent air flow over and around sterile areas. We have also purchased a smaller triangular trash bag frame that will sit in the corner of the room, behind the Mayo stand and away from the flow of the vent. There is a better distance between the trash receptacle and the sterile area now. These items were purchased and put in place by Toiny Schneider, Director of Operations on 8-24-15.

1. c. On 08-22-15, the Governing Body discussed the possibility of moving one of the autoclaves from the workroom to make more space for handling clean items after decontamination. This is not a reasonable option for processing instruments between cases as we need both autoclaves to perform safe procedures for our patients. However, we have moved the autoclaves closer to the door leaving more space between the sink and the autoclave doors. We will continue to leave the autoclave doors closed until all water is off, all counters and sinks are drained and decontaminated, and all instruments are wrapped, peeled, or organized on decontaminated sterilization trays for autoclaving. We will allow only one person at a time in the workroom as well, as there is not room for more than one staff member. When possible, we will use the disinfected back table to wrap instruments for autoclaving. This will offer the solution to handle clean items only in areas that have been decontaminated. It will add to the turnover of cases, but will address the issue of limited space and keep potential for spreading microorganisms and bacteria to a minimum.

1. d. An approved medical grade clipping device with disposable heads was approved by the Governing Body on 08-22-15 and ordered from Medico on 08-22-15 by Charlene Conilogue, Admin. We now have a safer way to do patient shaves as the heads allow for single use shaves. This will provide for optimal outcomes for patients as the risk for injury is reduced and cross contamination is eliminated.

1. e. On 08-22-15 all household cleaning items were removed from beneath the OR sink. They have been removed from the ASC as well. There are 2 mixtures of those at Idaho SurgiCenter North. They are Maxima and diluted Clorox solution. The Maxima will be mixed on the clinic side by Toiny Schneider, Director of Operations, and placed in a Maxima labeled spray bottle with SDS information, date it was mixed, and who mixed it attached to it. It will be stored for use at the ASC to disinfect flat surfaces, cords, and OR table. It will be stored under the sink in the OR and in a cupboard in the pre-operative room, and will be replaced monthly to ensure efficacy. The Clorox solution will be mixed as needed and not stored at the ASC. It will be mixed 1:10 when surfaces need to be cleansed of any enzymes. This will ensure that cleaners without labels and cleaners with expiration dates are not stored at the ASC which will prohibit unsafe use of cleaners by housekeeping staff and other employees with housekeeping responsibilities. It will also ensure that patients are not exposed to hazardous chemicals or cleaning solutions and will ensure that cleaning solutions remain strong enough to carry out the task they are designed for. Toiny Schneider, Director of Operations is responsible for this task and it was carried out on 08-25-15.

2. a. We have purchased enzymatic cleaner to be used during instrument decontamination. The instructions for use prohibit use of any detergent with it so the detergent has been removed from the ASC workroom. It is to be diluted at 1 oz. per gallon of hot water. Instruments should soak for a period of 5 minutes prior to scrubbing to loosen bioburden. All instruments whether they have been used or not will be cleaned with the enzymatic cleaner and processed the same way in order to address all instrumentation as being contaminated. The enzymatic cleaner was ordered by Charlene Conilogue, Administrator, on 08-25-15 and put it place in the workroom by Toiny Schneider, Director of Operations, on 09-08-15. Use of enzymatic cleaner will ensure the safest possible use of surgical items for patient procedures, protecting patients from exposure to infectious bacteria and microorganisms.

2. b. We have removed all scotch scrubbing pads that may leave fibers from the ASC workroom per AORN 2015 guidelines for use of abrasive devices. We will continue to use the approved metal brushes and nylon scrub brushes for scrubbing serrated instruments. Metal brushes will only be used if nylon brushes won't accomplish the task. Cords and non-immersable power pieces will be wiped down with a

lap sponge soaked in the cleaning solution of water and enzymatic cleaner and rinsed with a clean lap soaked in distilled water. We will use distilled water for rinsing disinfected instruments in order to reduce residue and protect instruments from corrosion and pitting. Per existing policy, after disinfecting and rinsing for each surgical case, we will dump the solution and water tubs, using a new tub of clean solution and water for each subsequent case. We will provide safer processing of instruments which translates to safer use and protection for patients against possible contaminants and exposure to endotoxins that may be carried in tap water. The scotch pads were removed on 09-11-15 by Charlene Conilogue, Admin. The extra distilled water necessary for rinsing instrumentation was purchased and placed in the workroom on 09-09-15 by Toiny Schneider, Director of Operations.

1. c. All instruments will be disinfected with enzymatic cleaning solution to ensure that bacterial growth doesn't occur between the time of cleaning and sterilization. Additionally, all instruments will be processed and not left on the shelf for any length of time other than the length of time it takes to wrap them for processing. After instruments are processed and dry, they will be removed from the autoclave and stored in the OR in cupboards marked "STERILE" in bins, per present policy.

After all instruments have been removed from the enzymatic solution, all cleaning brushes and drain baskets will be placed in the solution and scrubbed in the same manner. They will then be rinsed in the empty rinse container with distilled water, dried with disposable towels, and placed in a pouch for sterilization with a chemical indicator. This pouch of cleaning supplies will be autoclaved after all other peels have been processed and stored on an overhead shelf until the next surgery day. This process was suggested by our Infection Control Officer, Teri Fry, RN and implemented on 09-11-15. Charlene Conilogue prepared and presented Instrument Training instruction on 09-11-15 at Ms. Fry's request. It was completed and is documented in the Inservice Manual for all employees. This practice will ensure that all potential for cross contamination of re-useable supplies is kept at a minimum which will protect patients from exposure to microorganisms and improve patient outcomes.

1. d. Idaho SurgiCenter North will use approved single use wraps and dispose of them upon opening of packs. No wraps that have been previously used will be used in the future. All wraps that have been saved for use from packs have been discarded and we will not save these for future use at the ASC. This practice will meet the AORN 2015 guideline for Perioperative Practice regarding wrapping materials. These single use wraps are stored in a plastic covered bin in the workroom at the ASC. They were ordered and put in place on 08-25-15 by Toiny Schneider, Director of Operations.

1. e. On 08-22-15, the Governing Body ruled that no biohazardous waste will be poured down the sink or the toilet where patients or employees have potential exposure to hazardous waste. We have purchased approved disposable suction canisters with tight fitting lids and caps that will prevent leaks and exposure to employees and patients of biohazardous waste. Appropriate solidifier for biohazardous fluids was also purchased. These waste containers will be sealed after adding the solidifier and disposed of in marked biohazardous waste containers. The waste will be picked up per our policy and contract with a biohazardous waste service. The canisters and solidifier were ordered by Charlene Conilogue and delivered for use before our surgery day on 09-11-15. We used them that day per our new policy.

1. f. On 08-22-15, the Governing Body approved expenditures for the failed autoclave fan and missing printers for both autoclaves. Charlene Conilogue, Administrator, called a different repairman for autoclave issues [REDACTED] in SLC) and he performed an inspection on the fan stating that it only runs when the autoclave overheats, but that it is necessary for optimal

performance of the autoclave. A serviceman with ESP replaced the fan on 09-15-15. [REDACTED] also ordered printers for both of the autoclaves and the printer on the M11 was installed on 09-15-15. The printer that came for the M9 was damaged in shipping and is being re-ordered by the [REDACTED]. It will be installed as soon as it comes. Follow up was conducted on 09-16-15 conducted by Charlene Conilogue, Admin. Nothing has been shipped yet for the M9 as of 09-16-15.

1. g. On 08-22-15 (and before we found printers for the autoclaves) Governing Body ruled that we would use logs that included all necessary documentation in regard to sterilized loads. Charlene Conilogue created a log on 08-25-15 that included a record of the load number, temperature range of load, time in and out (establishing load length), which autoclave was used, load contents, load number, and which staff member processed the load. This meets the requirement in our policy to follow AORN 2015 Guidelines for Perioperative Practice. The staff members who are processing loads started using this log on 09-11-15. The printer tapes will be additional documentation of sterility of loads and proper processing of surgical packs and peels. This will ensure that patients receive optimal care in regard to use of surgical items during procedures while improving practices and providing safety to patients.

1. h. When Governing Body met on 08-22-15, it was decided that BI monitoring should be re-assessed and policies needed to be changed. The 4 patients referred to in the 2567 where the BIs were read on the day following implantation of hardware were called on 09-15-15 to follow up and be sure that there were no problems with any of the implants. Toiny Schneider made these patient calls on 09-15-15 and logged the calls in the Implant Follow-up Log. Ms. Schneider also audited the BI log to see if there were other patients who had had implants placed prior to the BI result documentation and those were called if they were discovered, and the calls were documented in the Implant Follow-up log as well. In the future, no staff member will be permitted to remove biologicals from the ASC. Our policy for running BIs was changed in the Infection Manual to read that control testing will take place prior to each surgery day. The BI loads are to be run in empty autoclaves with a control in the incubator not earlier than 48 and not later than 24 hours before the start of the surgery day. Implants to be used on surgery days are to be run with BIs after the test load is run and read no less than 24 hours before surgery day begins. This will provide ample time for BIs to be read and logged before implantation of devices in patients. Any devices brought in by implant reps are to be delivered Tuesday morning for implantation on Friday, this will give the staff time to run BIs on them, ensuring. Charlene Conilogue, Admin., will notify reps when implant cases are scheduled to ensure that timely delivery occurs. If reps don't deliver implants to the ASC by the time required, the implants will not be used.

1. i. On 08-22-15, the Governing Body audited the BI log sheet and ruled that the Autoclaves will be monitored with a BI Attest vial prior to each surgery day. Our revised policy for running BIs is in the Infection Manual to read that control testing will take place prior to each surgery day which may only be twice monthly. The BI loads are to be run in empty autoclaves with a control in the incubator not earlier than 48 and not later than 24 hours before the start of each surgery day. Also at that meeting, the Governing Body gave permission for the clinic side to use the autoclave when necessary with the following stipulation: If the clinic side uses the autoclaves, it is to be done in the window after autoclaving is finished on the surgery day and before the test load is run for the next surgery day. This will prevent cross contamination from the clinic side and provide optimal procedures for protection of patients from exposure to microorganisms and infectious bacteria. Charlene Conilogue, Administrator, made the changes to the Infection Control Manual on 08-25-15 and provided staff education at the Infection Control Officer's (Teri Fry, RN) request on 09-11-15 regarding use and documentation of BI results.

3. On 08-22-15 at the Special Governing Body meeting, it was decided that going forward we will contract with a healthcare accredited laundry service for laundering of patient linens and staff scrub wear in accordance with the 2015 AORN Guidelines for Perioperative Practice. Charlene Conilogue took bids from two different places and secured a contract with Ameripride out of Twin Falls on 09-15-15. All ASC staff will be required to wear this scrub wear. After meeting with the rep, we learned that we will be able to secure reports containing proof of monitoring at least twice yearly and those will be stored in our Ancillary Service Contract binder with the appropriate contract for service with Ameripride. These reports will address the standards listed in our Infection Manual. The agreement is in place, but due to the nature of the inventory we require, the first delivery will not take place until 10-12-15. Thereafter, the pickup and delivery day will be every other Monday to keep soiled laundry from sitting for long periods of time. The laundry to be picked up will not be stored at the ASC, but on the clinic side in an area designated for storage of Biohazardous waste. These changes were made to our Infection Control Manual by Charlene Conilogue, Administrator on 08-25-15. By contracting with an accredited laundry service provider, we hope to continue to provide an optimum product for patients and employees while meeting required standards.

#### **Q 242 Infection Control Program**

1. On 9-11-15 a Special Governing Body Meeting was held and Teri Fry, RN, our Infection Control Officer was present. The Governing Body stated that responsibility for Infection Control takes more time than Ms. Fry was currently dedicating to it. She agreed and committed to more effort which will require more time than 15%. She will dedicate 25% of her time at the ASC to monitoring activities that will include surveillance of staff and patients in regard to current trends in Infection Control. The job description in the Personnel Manual for Infection Control Officer lists the things that she will make part of her accounting in performance of her responsibility. They are:

- Conducts staff training to ensure constant implementation of Infection Control practices;
- Conducts surveillance for detecting the infection source for the purpose of prevention;
- Follows and investigates the incidents of nosocomial infections, generating reports and presenting them to the medical director;
- Monitors the execution of preventive measures and provides guidance to staff;
- Prepares quarterly statistical information for presentations in QAPI meetings as requested;
- Monitors and manages staff exposure incidents and infectious illnesses; and
- Implement necessary policies and procedures for infection control consistent with national standards and guidelines.

Additionally, The Governing Body granted her the opportunity for more education for this responsibility with compensation for travel, etc. Ms. Fry has researched educational opportunities that will make her the expert for Infection Control at Idaho SurgiCenter North. She will have at least 4 credit hours of training in place by 09-24-15 and complete 1 credit hour of training monthly thereafter. As a QAPI committee member, she will be given time at each quarterly meeting to address concerns and inform staff of trends and will be expected to contribute to study and benchmarking activities by providing data collection for evaluation. Governing Body will assess the Infection Control Program under Ms. Fry's direction annually and make needed changes as necessary. She will be accountable to the Governing Body going forward and will take a more active role in this aspect of operations of Idaho SurgiCenter North.

2. When the Governing Body met on 09-11-15, they changed the policy that states that patients would be seen within 48 hours after surgery for assessment to match our practice of calling the patient within 24 hours of their surgical procedure. Patients have the after-hours phone number at their disposal to call if any problems should arise; it rings directly to Dr. Quinton's phone. The next time patients are evaluated is in the office the week after surgery on either a Wednesday or a Thursday for dressing changes, and they are seen by Dr. Quinton. The 2<sup>nd</sup> post op visit is 12-13 days after surgery at the time that sutures are removed. This schedule of visits is working and is a good way for us to monitor the progress and potential for problems with surgery patients. It is the best way that our staff has of providing care for patients and ensuring that their recovery is on track. This was changed in the Nursing Manual by Charlene Conilogue, Administrator on 09-15-15.

3. The Governing Body granted the Infection Control Officer, Teri Fry RN, the opportunity for more education for this responsibility. As a QAPI committee member, she will be given time at each quarterly meeting to address concerns and inform staff of trends and will be expected to contribute to study and benchmarking activities by providing data collection for evaluation. She will be accountable to the Governing Body going forward, assessing the program under her direction and will take a more active role in this aspect of operations at Idaho SurgiCenter North. To this point, and since the survey conducted on 08-21-15, she has taken an active role in Infection Control Policy updates and changes demonstrating that she is capable of managing Infection Control at the facility. She was interviewed as part of a performance evaluation by the Charlene Conilogue, Administrator, as a member of the Governing Body and committed to more concentrated efforts on 09-11-15. This performance review is found in Ms. Fry's personnel file. Follow up to this evaluation will take place within 3 months by way of a performance review conducted by Ms. Conilogue, Administrator, no later than December 11, 2015. This evaluation will be presented to the Governing Body for review after completion.

#### **Q 243 416.51 (b) (1) INFECTION CONTROL PROGRAM DIRECTION**

On 9-11-15 a Special Governing Body Meeting was held and Teri Fry, RN, our Infection Control Officer was present. The Governing Body stated that responsibility for Infection Control takes more time than Ms. Fry was currently dedicating to it. She agreed and committed to more effort which will require more time than 15%. She will dedicate 25 percent of her time to monitoring activities that will include surveillance of staff and patients in regard to current trends in Infection Control. The Governing Body also granted her the opportunity for more education for this responsibility with compensation for travel, etc. Ms. Fry is currently researching educational opportunities that will make her the expert on Infection Control at Idaho SurgiCenter North. Charlene Conilogue followed up on 09-16-15 with Ms Fry in regard to training opportunities. Ms. Fry has researched educational opportunities that will make her the expert on Infection Control at Idaho SurgiCenter North. She will have at least 4 credit hours of training in place by 09-24-15 and complete 1 credit hour of training monthly thereafter. A log of training will be maintained in her personnel file.